

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

Office of Biotechnology Activities
National Institutes of Health
6705 Rockledge Drive
Suite 750, MSC 7985
Bethesda, MD 20892-7985
(301) 496-9838 (Phone)
(301) 496-9839 (Fax)
http://oba.od.nih.gov/oba

September 21, 2011

Name M.S., CIH, CBSP
Institutional Biosafety Officer
Mount Sinai School of Medicine
One Gustave L. Levy Place
Box 1155
Atran-Berg Building B2 Room 56D
New York, NY 10029

Dear Mr. Name:

Thank you for your September 2, 2011, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing a September 2, 2011, incident in which a researcher at the Mount Sinai School of Medicine was bitten by a ferret that had been previously inoculated with a recombinant form of 1918 influenza virus. The inoculation occurred approximately three days prior to this incident. According to your report, the researcher immediately washed the wound with 70-percent alcohol, showered out of the facility, and contacted the biological safety officer. The researcher was examined by the occupational health physician and was administered the 2011 batch of the Valence influenza vaccine and prescribed a course of Tamiflu. As per Mount Sinai protocol, the researcher was quarantined at home for seven days following the exposure. According to your report, it was verified that the researcher lived alone before being discharged to home-quarantine. The researcher was also instructed to use an N95 respirator if, during the home-quarantine, he needed outside medical assistance. The researcher was also instructed to take his temperature in the morning and evening and report the results, via telephone, to the occupational health physician. The likelihood of illness from this exposure was judged to be remote, but the researcher was monitored until the incubation period for disease had passed. The researcher subsequently showed no symptoms of illness and returned to work on September 9, 2011.

The actions taken in response to this incident by Mount Sinai Medical Center appear appropriate. No further information is required at this time. Please contact OBA staff by email at oba@od.nih.gov or by telephone at (301) 496-9838 if you have any questions.

Sincerely,

Jacqueline Corrigan-Curay, M.D., J.D.
Acting Director
Office of Biotechnology Activities

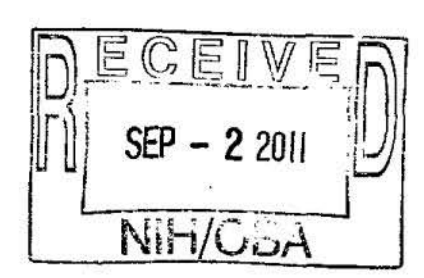
cc: [redacted] M.D., Ph.D., Assistant Professor of Medicine, Mount Sinai School of Medicine
[redacted] Senior Director, Environmental Health and Safety, Mount Sinai School of Medicine
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Ryan Bayha, Outreach and Education Analyst, Office of Biotechnology Activities, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), Office of Biotechnology Activities, NIH

9/21



MOUNT SINAI
SCHOOL OF
MEDICINE





DATE ____September 2, 2011______________________

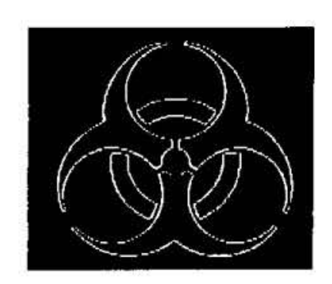
TO Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985 (20817 for non-USPS mail), 3 01-496-9838, 301-496-9839 (fax).

FAX# 301- 496-9839 (fax).
SUBJ: Mount Sinai School of Medicine /SA&T Renewal

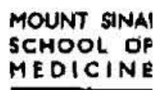
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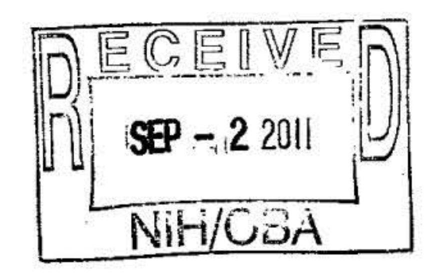
COMMENTS:
See Attached Letter for information regarding Ferret bite with Modified GMO 1918 Influenza; CDC has also been notified through the Select Agent Program: Expanded contact Info at bottom of letter

Name MS, CIH, CBSP, SM(NRM)
Institutional Biosafety Officer
Mount Sinai School of Medicine
One Gustave L. Levy Place
Box 1162
Atran Berg B2—56D
New York, New York 10029
212 241 5169 phone
212 241 6695 Fax











Institutional Biosafety Program

September 2, 2011
National Institutes of Health / Office of Biotechnology

Greetings:
I received a call at @14 58 hrs from Name stating that he had been bitten by a ferret, 3 days post- inoculation with a mutant form of the 1918 (Spanish) Influenza. At present he is waiting to be seen by Dr. Name the Alternate Responsible Official, BSL-3 Director and ID Physician in order to be evaluated.

Name is up to date on his flu shot, and noted that the ferret's incisor barely broke the skin of his left thumb (hands were double-gloved). He immediately washed the site with 70% alcohol, showered out of the facility as per standard protocol and contacted me. I in turn notified Dr. Name who will relay back to me his findings.

Since this is a genetically modified Influenza, I have to notify the NIH Office of Biotechnology Activities as well as the Centers for Disease Control. Realistically, if we were to see an infection it would take two-four days incubation time. Bite-wound inoculation is not a standard exposure route, and Name stated that the ferret was not moribund, but to the contrary was energetic and health (not displaying any signs of illness). We will institute the standard operating procedure of checking daily for elevated temperature / fever, sore throat and the usual flu-like symptoms. Name will also have to begin taking Tamiflu prophylactically.

Dr. Daefler stated to me he is on call all weekend as part of his rotation in Infectious Disease, and would be able to monitor Name closely over the weekend if any illness develops. The likelihood is extremely remote, but we will not be sure until Name is past the incubation period without any sequelae.

I will keep you updated with regard to any further developments. At present, I will relay exactly what I reported to you to the two agencies.

Name

Name MS, MSHS, CIH, CBSP, SM(NRM)
Institutional Biosafety Officer
Environmental Health and Safety

Tel: 212 241 5169
Pager: Personal Info
Fax: 212 241 6695
BB: Personal Info



MOUNT SINAI
SCHOOL OF
MEDICINE

FAX



DATE September 8, 2011

TO **Ryan T. Bayha**
Outreach and Education Analyst
Office of Biotechnology Activities
Office of Science Policy
National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892-7985
(301) 496-9838 (phone)
(301) 496-9839 (fax)

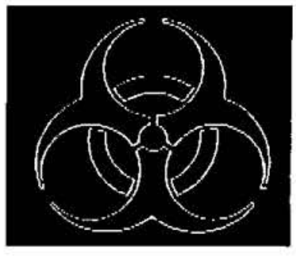
FAX# **(301) 496-9839**

SUBJ: RE: Form 3 Report – Name Ferret Bite-9/2/2011

NO. OF PAGES + COVER 1+2=3

COMMENTS: Select Agent Form 3 Completed for the incident reported by Faxl and phone.

Name MS, CIH, CBSP, SM(NRCM)
Institutional Biosafety Officer
Mount Sinai School of Medicine
One Gustave L. Levy Place
Box 1162
Atran Berg B2—56D
New York, New York 10029
212 241 5169 phone
212 241 6695 Fax





REPORT OF THEFT, LOSS, OR RELEASE OF SELECT AGENTS AND TOXINS (APHIS/CDC FORM 3)

FORM APPROVED
OMB NO. 0579-0213
OMB NO. 0920-0576
EXP DATE 12/31/2011

Read all instructions carefully before completing the report. Answer all items completely and type or print in ink. The report must be signed and submitted to either APHIS or CDC within 7 days of the theft, loss or release:

Animal and Plant Health Inspection Service
Agricultural Select Agent Program
4700 River Road Unit 2, Mailstop 22, Cubicle 1A07
Riverdale, MD 20737
FAX: 301-734-3652
E-mail: Agricultural.Select.Agent.Program@aphis.usda.gov

Centers for Disease Control and Prevention
Division of Select Agents and Toxins
1600 Clifton Road NE, Mailstop A-46
Atlanta, GA 30333
FAX: 404-718-2096
Email: lrsat@cdc.gov

SECTION 1 – TO BE COMPLETED BY ALL ENTITIES

1. Entity name: Mount Sinai School of Medicine		2. Entity registration number (if applicable): CDC050563	
3. Entity address (NOT a post office address): One Gustave L. Levy Place	4. City: New York City	5. State: NY	6. Zip Code: 10029
7. Responsible Official (RO) or Facility Director First: Name MI: Name Last: Name	8. Telephone #: 212 241 5169		
9. FAX #: 212 241 6695	10. E-mail address: Name @mssm.edu		
11. RO or Facility Director address (NOT a post office address): Same as entity-Box 1162	12. City: New York City	13. State: NY	14. Zip Code: 10029
15. Type of incident: ☐ Theft ☐ Loss ☐ Release / 16. Immediate notification provided to: ☐ APHIS ☑ CDC	17. Date of immediate notification: 09/02/2011	18. Type of immediate notification: ☑ E-mail ☐ Fax ☐ Telephone	

19. An internal review of laboratory procedures and policies has been initiated to prevent recurrences of theft/loss/release of select agents and toxins at this entity: ☐ No ☑ Yes (If yes, please provide additional details in an attachment.)

SECTION 2 – TO BE COMPLETED BY ALL ENTITIES

LIST OF SELECT AGENTS AND TOXINS LOST, STOLEN OR RELEASED (attach additional sheets if necessary)

	20. Select agents and/or toxins:	21. Characterization of agent:	22. Number of vials:	23. Form (powder/liquid/slant):	24. Volume or wt of vial contents (e.g., mL, mg, ng):
A	Reconstructed 1918 influenza virus	3-days post inoculation /ferret	0		0.00
B					
C					
D					

25. Date and time of incident: 09/02/2011	26. Date of last inventory:	27. Name of principal investigator responsible for laboratory with select agents and toxins: First: Adolfo MI: Last: Garcia-Sastre

28. Location of incident (building and room #): Annenberg 17	29. Location of incident (within room (e.g., freezer, incubator)): 294 DD	30. Biosafety level of laboratory where incident occurred: ABSL3	31. Agent was recovered (theft/loss): ☑ No ☐ Yes

32. Provide a detailed summary of events including a timeline of events and name and telephone numbers of agencies notified. The summary should also include description of containers (e.g., size, color, type, brand, and any symbols or markings), supporting documentation (e.g., access and inventory records), identified weaknesses, and any corrective actions taken (attach additional sheets if necessary):

I received a call at @14 58 hrs from Name stating that he had been bitten on the left thumb (@ 13 30 hrs by a ferret, which was 3 days post- inoculation with a mutant form of the 1918 (Spanish) Influenza. The incisor broke through the double set of gloves and scored the skin 9not a deep puncture wound). He provided first aid by expressing the wound and washing with 70% ethanol, and showered out of the EPF facility as per protocol. He was seen by Dr. Name the Alternate Responsible Official, BSL-3 Director and ID Physician who started Dr. Name on Tamiflu and administered the newly received Influenza vaccine (2011 valence) that is being administered to health care providers. Name received the mandatory flu vaccine in October, 2010]. As of today (9/7/2011) there have been no sequelae, however he is in quarantine until 9/7/2011 and reporting his health status twice per diem to Dr. Simon Daefler.

☐ Continued as an attachment

(CDC Adobe Acrobat 9.0 Electronic Version, 1/2009)

RECEIVED
SEP - 8 2011
NIH/OSA

SECTION 3 – IF THE INCIDENT OCCURRED DURING TRANSFER PROVIDE THE FOLLOWING INFORMATION AND INCLUDE A COPY OF THE RELEVANT APHIS/CDC FORM 2

33. Transfer authorization number from APHIS/CDC Form 2: NA	34. Date shipped:
35. Name of carrier:	36. Airway bill number/bill of lading number/tracking number:

37. Package description (size, shape, description of packaging including number and type of inner packages; attach additional sheets if necessary):
Not Applicable

38. Package with select agents and toxins received by requestor: ☐ No ☐ Yes If yes, date of receipt:	39. Package with select agents and toxins appears to have been opened: ☐ No ☐ Yes (If Yes, include in explanation above for Box #37)
40. Sender was contacted regarding incident: ☐ No ☐ Yes	41. Carrier/courier was contacted regarding incident: ☐ No ☐ Yes

SECTION 4 – TO BE COMPLETED ONLY FOR RELEASE OF SELECT AGENTS AND TOXINS

42. Hazards posed by release: ☐ No ☑ Yes (If Yes, explain. Attach additional sheets if necessary.)
Potential for infection with 1918 influenza; route of exposure and load of potential 1918 influenza virus has little potential to cause an active infection. Nonetheless, this incident is being tracked as a significant exposure until the full 7 days is reached.

43. Exposures: ☐ No ☑ Yes (If Yes, provide number of persons, animals, and plants exposed. Attach additional sheets if necessary.)
One individual was bitten by an inculated ferret, 3-days post inoculation.

44. Area was decontaminated: ☐ No ☑ Yes (If Yes, explain. Attach additional sheets if necessary.)
Individual provided immediate wound cleaning and antisepsis, followed by mandatory shower-out decontamination.

45. Medical treatment was provided: ☐ No ☑ Yes (If Yes, explain. Attach additional sheets if necessary.)
Tamiflu regimen plus inoculation with 2011 Valence Influenza Vaccine.

I hereby certify that the information contained on this form is true and correct to the best of my knowledge. I understand that if I knowingly provide a false statement on any part of this form, or its attachments, I may be subject to criminal fines and/or imprisonment. I further understand that violations of 7 CFR 331, 9 CFR 121, and 42 CFR 73 may result in civil or criminal penalties, including imprisonment.

Signature of Respondent: Name Title: Biosafety officer and RO

Typed or printed name of Respondent: Name MS, MSHS, CBSP, SM(NRCM) Date: 09/07/2011

Public reporting burden: Public reporting burden of providing this information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-0576).